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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,637	01/29/2004	Michael D. Mason	2731/103	5420

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BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER	
REIMERS, ANNETTE R	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,637	MASON, MICHAEL D.	
	Examiner	Art Unit	
	Annette R. Reimers	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirayama et al. (U.S. Patent Number 4,946,378).

Hirayama et al. disclose a method for fusing a first vertebra to a second adjacent vertebra (see figure 3). The method comprises providing an implant, e.g. 10 of figure 1 below, comprising a body, e.g. 3 of figure 1 below, having first and second opposite surfaces (see figure 1 below), wherein each of the surfaces includes at least one protruding member, e.g. 1 of figure 1 below, for securing the body to an adjacent vertebra and wherein the implant has sufficient tensile and sheer strength to permit fusion of the vertebrae (see column 2 lines 18-20) and each of the surfaces and protruding members includes a bioactive coating, e.g. 4 of figure 1 below.

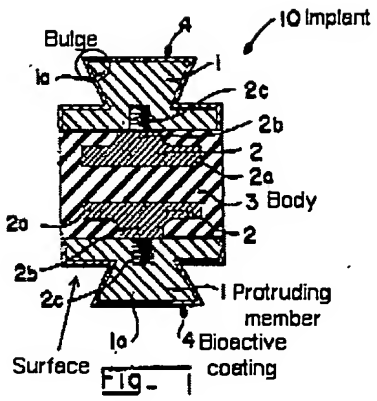

Fig. 1

The method further comprises forming at least one keyway in the first vertebra corresponding to each of the at least one protruding members on the first surface and at least one keyway in the second vertebra corresponding to each of the at least one protruding members on the second surface (see figure 3 and column 3 lines 34-40). In addition, the implant is inserted between the first vertebrae and the second vertebrae in a manner so that each protruding member slides into the corresponding keyway (see column 2 lines 6-8), such that fusion of the vertebrae is achieved without a bone graft. (see column 1 lines 44-50).

Regarding claims 2 and 4-5, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961).

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (U.S. Patent Number 5,888,227).

Cottle discloses a method for fusing a first vertebra to a second adjacent vertebra. The method comprises providing an implant, e.g. 1 of figure 4, comprising a body (see figure 4), having first and second opposite surfaces, e.g. 11 and 12 of figure 4, wherein each body opposite surface includes exactly two protruding members, e.g. 18 of figures 4 and 7, for securing the body to an adjacent vertebra and wherein the implant has sufficient tensile and sheer strength to permit fusion of the vertebrae (see column 2 lines 46-50) and each of the surfaces and protruding members includes a bioactive coating (see column 2 lines 54-57).

Cottle discloses forming the keyway (see column 2 lines 64-67), such that fusion of the vertebrae is achieved without a bone graft. (see column 1 lines 23-29 and 45-49). Although bone graft material is suggested, the use of bone graft material is discretionary, i.e. compressibility of bone material, which may, not shall, be introduced into the cage (see column 3 lines 28-29).

Regarding claims 2 and 4-5, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961).

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Fraser et al. (U.S. Patent Number 6,592,624).

Fraser et al. disclose a method for fusing a first vertebra to a second adjacent vertebra (see figure 11). The method comprises providing an implant, e.g. 10 of figure 1, comprising a body, e.g. 16 of figure 1, having first and second opposite surfaces, e.g. 42 and 46 of figure 1, wherein each body opposite surface includes exactly two protruding members, e.g. 22 and 23 of figure 1, for securing the body to an adjacent vertebra. In addition, the protruding members include a bioactive coating. Fraser discloses forming the keyway (see figure 11), such that fusion of the vertebrae is achieved without a bone graft (see column 5 lines 49-61). The method of Fraser et al. also discloses at least one protruding member of the implant that includes a pair of bulges (see 18 of figure 1 and column 4 lines 19-24).

Regarding claims 2 and 4-5, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961).

Response to Arguments

Applicant's arguments filed June 9, 2005 have been fully considered, but they are not persuasive. In response to applicant's argument that the Hirayama et al. and Fraser et al. references do not achieve fusion of the vertebrae, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Both the Hirayama et al. and Fraser et al. devices are capable of achieving fusion of the vertebrae. Regarding the Cottle reference, there is a suggestion of the formation of keyways (see column 2, lines 64-67).

Applicant's arguments in the Declaration filed on June 9, 2005 have been fully considered, but they are not persuasive. As stated above, in response to applicant's argument that the Hirayama et al. and Fraser et al. references do not achieve fusion of the vertebrae, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Both the Hirayama et al. and Fraser et al. devices are capable of achieving fusion of the vertebrae. In response to applicant's arguments regarding relative rigid materials of the implant body, the extent of fixation, and the effect of the shape of the protruding member on vertebral fixation for the implant, the limitations on which the applicant relies

are not stated in the claims. Therefore, it is irrelevant whether the references include those features or not.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
PRIMARY EXAMINER